Cytori Reports Fourth Quarter and Full Year 2018 Business and Financial Results

April 1, 2019

Strategic focus on building a leading oncology company / Lorem Vascular cell therapy transaction yields $4MM

Letter of intent for ATI-0918 filed with EMEA

SAN DIEGO, April 01, 2019 (GLOBE NEWSWIRE) -- Cytori Therapeutics (NASDAQ: CYTX) ("Cytori" or the "Company") today announced its fourth quarter and year-end 2018 financial results and provided updates on corporate activities. Also announced was a transaction to divest certain cell therapy assets to Lorem Vascular of Melbourne, Australia yielding $4MM in non-dilutive funding to the Company.

Fourth quarter 2018 net loss was $2.2 million, or $0.16 per share. Operating cash burn for the fourth quarter of 2018 was approximately $2.5 million. Cytori ended the year with approximately $5.3 million of cash and cash equivalents.

"This transaction sale accomplishes a number of important objectives for the company," said Dr. Marc Hedrick, Cytori President & Chief Executive Officer. "Most critically it allows us to further increase the focus on our clinical stage oncology pipeline while bringing in non-dilutive capital. We also are able to maintain our most valuable cell therapy assets, including Japan that has a forthcoming trial readout in our ADRESU trial."

Our lead clinical stage asset, Doxorubicin Hydrochloride Cytori, formerly called ATI-0918, is an important potential therapy for Breast and Ovarian Cancer, Multiple Myeloma and Kaposi's Sarcoma. Our current development program is focused in Europe where we believe there is a potential market opportunity of $120 million annually. In Q1 2019, Cytori submitted a letter of intent to file a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for Doxorubicin Hydrochloride Cytori. Doxorubicin Hydrochloride Cytori is being developed as a generic version of Janssen's Caelyx pegylated liposomal doxorubicin. The Company continues to evaluate potential development and commercialization partnering opportunities for Doxorubicin Hydrochloride Cytori with a focus on Europe and China. European approval and launch of Doxorubicin Hydrochloride Cytori is projected to be in late 2020.

Our second clinical stage oncology focused asset is ATI-1123, a phase II ready, patented, albumin-stabilized pegylated liposomal docetaxel. In 2018, the Company received an orphan drug designation from the U.S. FDA for the indication of small cell lung cancer and is pursuing a 505(b)(2) new drug application (NDA) pathway in the U.S. which may offer an accelerated clinical timeline and lower development cost. The Company is exploring near term development strategies and intends to advance this program aggressively in 2019.

Cytori's ADRESU pivotal urinary incontinence trial using Cytori Cell Therapy has completed enrollment and anticipates data read out in the second quarter of 2019. If the data is positive, Cytori intends to seek expedited approval and reimbursement for the Japanese market for this indication. In Q1 2019, Cytori received approval from the United States Food & Drug Administration to expand the enrollment criteria for its RELIEF clinical trial of intravenously delivered Cytori Cell Therapy for patients with severe burn injuries.

Q4 2018 and Full Year 2018 Financial Performance

- Q4 2018 and full year operating cash burn was $2.5 million and $12.0 million, compared to $4.2 million and $18.1 million for the same periods in 2017, respectively.
- Q4 2018 and full year product revenues were $0.4 million and $2.7 million, compared to $0.7 million and $2.7 million for the same periods in 2017, respectively.
- Q4 2018 and full year contract revenues were $0.7 million and $3.0 million, compared to $0.9 million and $3.7 million for the same periods in 2017, respectively.
- Cash and debt principal balances at December 31, 2018 were approximately $5.3 million and $13.0 million, respectively.
- Q4 2018 adjusted net loss was $2.8 million or $0.20 per share, compared to a net loss of $4.3 million or $1.00 per share for the same period in 2017. The adjusted net loss excludes a non-cash beneficial conversion feature (a non gaap measure) related to the issuance of our Series C convertible preferred shares in the third quarter of 2018 of $2.5 million, as well as a credit of $0.6 million related to a change in fair value of warrant liability (a non gaap measure). Q4 2018 net loss allocable to common stockholders was $2.2 million, or $0.16 per share.
- Full year 2018 adjusted net loss was $14.9 million or $1.71 per share, compared to $21.0 million or $6.48 per share for the same period in 2017. The adjusted net loss excludes a non-cash beneficial conversion feature (a non gaap measure) related to the issuance of our Series C convertible preferred shares in the third quarter of 2018 of $2.5 million, as well as a credit of $2.2 million related to a change in fair value of warrant liability (a non gaap measure). Full year 2018 net loss allocable to common stockholders was $15.1 million, or $1.74 per share.

Selected Key Anticipated Milestones:

- Doxorubicin Hydrochloride Cytori: File Market Authorization Application to the European Medicines Agency in late 2019 or early 2020.
- ATI-1123: Clarify the FDA 505(b)(2) pathway applicability and announce clinical development plan in mid 2019.
- Cell Therapy Japan: Report ADRESU urinary incontinence pivotal clinical trial results in Q2 2019.

Management Conference Call Webcast

Cytori will host a management conference call at 5:30 p.m. Eastern Time today to further discuss its progress. The webcast will be available live and by replay two hours after the call and may be accessed under "Webcasts" in the Investor Relations section of Cytori's website. If you are unable to access the webcast, you may dial in to the call at +1.877.402.3914, Conference ID: 8766078.

About Cytori

Cytori is developing, manufacturing, and commercializing nanoparticle-delivered oncology drugs and autologous adipose-derived regenerative cell (ADRC) therapies within its Nanomedicine™ and Cell Therapy™ franchises, respectively. Cytori Nanomedicine™ is focused on the liposom encapsulation of anti-neoplastic chemotherapy agents, which may enable the effective delivery of the agents to target sites while reducing systemic toxicity. The Cytori Nanomedicine™ product pipeline consists of Doxorubicin Hydrochloride Cytori, a pegylated liposomal doxorubicin hydrochloride for breast cancer, ovarian cancer, multiple myeloma, and Kaposi's sarcoma, a complex/hybrid generic drug, and ATI-1123 patented albumin-stabilized pegylated liposomal docetaxel for multiple solid tumors. Cytori Cell Therapy™, prepared within several hours with the proprietary Celution® System and administered to the patient the same day, has been shown in preclinical and clinical studies to act principally by improving blood flow, modulating the immune system, and facilitating wound repair. As a result, Cytori Cell Therapy™ may provide benefits across multiple disease states and can be made available to the physician and patient at the point-of-care. For more information, visit www.cytori.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release includes forward-looking statements that involve known and unknown risks and uncertainties. All statements, other than historical facts, are forward looking statements. Such statements, including, without limitation, statements regarding anticipated commercial launch of our Doxorubicin Hydrochloride Cytori drug candidate (and timing thereof); completion of manufacturing activities necessary to submit an MAA to the EMA for our Doxorubicin Hydrochloride Cytori drug candidate; are subject to risks and uncertainties that could cause our actual results and financial position to differ materially. Some of these risks include clinical, pre-clinical and regulatory uncertainties, such as those associated with conduct and completion of the Company-sponsored RELIEF thermal burn trial, as well as the Company's anticipated submission of data to the EMA from the previously completed bioequivalency trial for Doxorubicin Hydrochloride Cytori. We also face risks that investigator-initiated trials using our Cytori Cell Therapy fail to fully enroll or otherwise are conducted in a manner that ultimately is injurious to our business. We also face the risk that we will be unable to time successfully manufacture our Doxorubicin Hydrochloride Cytori drug candidate in time to meet our projected timeline for submission of an MAA to the EMA, or at all. Some of these risks also include risks relating to regulatory challenges the Company faces (including the U.S., EU, China, Japan and its other key geographies) due to a number of factors including novelty of the Company's technology and product offerings, changes in and /or evolution of regulatory approaches to cellular therapeutics like the Company's in its key geographies, and similar matters. It is possible that the Company could face unexpected revenue shortfalls, expense increases or other occurrences that adversely affect our cash burn and cash management strategies. Further the Company face risks pertaining to dependence on third party performance and approvals (including performance of investigator-initiated trials, outcome of BARDA's review of the Company's proposed burn wound trial pursuant to its contract with BARDA, and outcome of the EMA's review of our Doxorubicin Hydrochloride Cytori MAA); performance and acceptance of the Company's products in clinical studies/trials and in the marketplace (including commercial acceptance of the Company's products in Japan and other markets where are products are commercially available, and similar risks); material changes in the marketplace that could adversely impact revenue projections (including changes in market perceptions of the Company's products, and introduction of competitive products); unexpected costs and expenses that could adversely impact liquidity and shorten the Company's current liquidity projections (which could in turn require the Company to seek additional debt or equity capital sooner than currently anticipated); the Company's reliance on key personnel; the Company's ability to identify and develop new programs or assets to expand the Company's clinical pipeline; the right of the U.S. government (BARDA) to cut or terminate further support of the thermal burn injury program (including any decision by BARDA not to proceed with our proposed thermal burn trial); the Company's abilities to capitalize on its internal restructuring and achieve break-even or profitability (or to continue to reduce our operating losses); and other risks and uncertainties described under the "Risk Factors" in Cytori's Securities and Exchange Commission Filings, included in the Company's annual and quarterly reports.

There may be events in the future that the Company is unable to predict, or over which it has no control, and its business, financial condition, results of operations and prospects may change in the future. The Company assumes no responsibility to update or revise any forward-looking statements to reflect events, trends or circumstances after the date they are made unless the Company has an obligation under U.S. Federal securities laws to do so.

CYTORI THERAPEUTICS, INC.
CONSOLIDATED CONDENSED BALANCE SHEETS
(UNAUDITED)
(in thousands, except share and par value data)

	As of December31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,261	$ 9,550
Accounts receivable, net of reserves of $185 in 2018 and $167 in 2017	286	145

Restricted cash	40	675
Inventories, net	2,947	3,183
Other current assets	1,114	1,311
Total current assets	9,648	14,864
Property and equipment, net	2,559	3,052
Other assets	1,905	2,570
Intangibles, net	5,957	7,207
Goodwill	3,922	3,922
Total assets	$ 23,991	$ 31,615
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,357	$ 4,790
Current portion of long-term obligations, net of discount	14,202	13,624
Total current liabilities	17,559	18,414
Deferred revenues	167	94
Long-term deferred rent and other	124	107
Warrant liability	916	—
Total liabilities	18,766	18,615
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 30,223 shares issued; 4,606 and 2,431 shares outstanding in 2018 and 2017, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 14,830,414 and 5,782,573 shares issued and outstanding in 2018 and 2017, respectively	15	6
Additional paid-in capital	418,375	413,356
Accumulated other comprehensive income	1,218	1,387
Accumulated deficit	(414,383)	(401,749)
Total stockholders' equity	5,225	13,000
Total liabilities and stockholders' equity	$ 23,991	$ 31,615

CYTORI THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(in thousands, except share and per share data)

	For the Years Ended December 31,

	2018	2017
Revenues:		
Product	$ 2,671	$ 2,689
License	1,000	—
	3,671	2,689
Cost of product revenues	1,148	1,318
Amortization of intangible assets	1,225	1,225
Gross profit	1,298	146
Development revenues:		
Government contracts and other	2,983	3,722
	2,983	3,722
Operating expenses:		
Research and development	8,622	11,678
Sales and marketing	2,018	3,593
General and administrative	6,339	7,594
In process research and development acquired from Azaya	—	1,686
Total operating expenses	16,979	24,551
Operating loss	(12,698)	(20,683)
Other income (expense):		
Interest income	43	33
Interest expense	(1,922)	(2,049)
Other income, net	180	13
Change in fair value of warrants	2,233	—
Issuance cost of warrants	(470)	—
Total other expense	64	(2,003)
Net loss	$ (12,634)	$ (22,686)
Beneficial conversion feature for convertible preferred stock	(2,487)	(3,977)
Net loss allocable to common stockholders	$ (15,121)	$ (26,663)
Basic and diluted net loss per share allocable to common stockholders	$ (1.74)	$ (8.23)
Basic and diluted weighted average shares used in calculating net loss per share allocable to common stockholders	8,692,551	3,238,983
Comprehensive loss:		
Net loss	$ (12,634)	$ (22,686)
Other comprehensive income – foreign currency translation adjustments	(169)	129
Comprehensive loss	$ (12,803)	$ (22,557)

CYTORI THERAPEUTICS, INC.
CONSOLIDATED CONDENSED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(in thousands)

	For the Years Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (12,634)	$ (22,686)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,004	2,151
Amortization of deferred financing costs and debt discount	578	707
In process research and development acquired from Azaya Therapeutics	—	1,686
Change in fair value of warrants	(2,233)	—
Allocation of issuance cost associated with warrants	470	—
Provision for doubtful accounts	18	—
Provision for excess inventory	463	340
Share-based compensation expense	355	753
Loss (gain) on asset disposal	36	(42)
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(173)	1,129
Inventories	475	251
Other current assets	85	(593)
Other assets	23	(94)
Accounts payable and accrued expenses	(1,532)	(1,817)
Deferred revenues	73	(3)
Long-term deferred rent and other	17	90
Net cash used in operating activities	(11,975)	(18,128)
Cash flows from investing activities:		
Purchases of property and equipment	(133)	(295)
Proceeds from sale of assets	—	113
Purchase of long-lived assets as part of Azaya Therapeutics' acquisition	—	(1,201)
Net cash used in investing activities	(133)	(1,383)
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(4,720)
Financed capital expenditures	(66)	—
Proceeds from sale of common and preferred stock	8,766	23,613
Costs from sale of common and preferred stock	(1,532)	(2,078)

Net cash provided by financing activities	7,168	16,815
Effect of exchange rate changes on cash and cash equivalents	16	11
Net decrease in cash and cash equivalents	(4,924)	(2,685)
Cash, cash equivalents, and restricted cash at beginning of period	10,225	12,910
Cash, cash equivalents, and restricted cash at end of period	$ 5,301	$ 10,225

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Source: Cytori Therapeutics Inc.